

1 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
2 APPLICATION
3 FOR
4 LETTERS PATENT
5 FOR
6 ENDOVASCULAR SUPPORT DEVICE AND METHOD
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19 SPECIFICATION

20 *B1* Field of the Invention

21 The present invention relates generally to medical devices, and particularly
22 relates to implantable devices for treating narrowing of coronary or peripheral vessels
23 in humans.

24 Background of the Invention

25 Cardiovascular disease, including atherosclerosis, is the leading cause of death
26 in the U.S. The medical community has developed a number of methods for treating
27 coronary heart disease, some of which are specifically designed to treat the
28 complications resulting from atherosclerosis and other forms of coronary arterial
29 narrowing.

30 The most impelling development in the past decade for treating atherosclerosis
31 and other forms of coronary narrowing is percutaneous transluminal coronary
32 angioplasty, hereinafter referred to simply as "angioplasty" or "PTCA". The objective

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1 in angioplasty is to enlarge the lumen of the affected coronary artery by radial
2 hydraulic expansion. The procedure is accomplished by inflating a balloon within the
3 narrowed lumen of the coronary artery. Radial expansion of the coronary artery
4 occurs in several different dimensions and is related to the nature of the plaque.
5 Soft, fatty plaque deposits are flattened by the balloon and hardened deposits are
6 cracked and split to enlarge the lumen. The wall of the artery itself is also stretched
7 when the balloon is inflated.

8 PTCA is performed as follows: A thin-walled, hollow guiding catheter is
9 typically introduced into the body via a relatively large vessel, such as the femoral
10 artery in the groin area or the brachial artery in the arm. Access to the femoral
11 artery is achieved by introducing a large bore needle directly into the femoral artery,
12 a procedure known as the Seldinger Technique. Once access to the femoral artery
13 is achieved, a short hollow sheath is inserted to maintain a passageway during
14 PTCA. The flexible guiding catheter, which is typically polymer coated, and lined with
15 Teflon, is inserted through the sheath into the femoral artery. The guiding catheter
16 is advanced through the femoral artery into the iliac artery and into the ascending
17 aorta. Further advancement of the flexible catheter involves the negotiation of an
18 approximately 180 degree turn through the aortic arch to allow the guiding catheter
19 to descend into the aortic cusp where entry may be gained to either the left or the
20 right coronary artery, as desired.

21 After the guiding catheter is advanced to the ostium of the coronary artery to
22 be treated by PTCA, a flexible guidewire is inserted into the guiding catheter through
23 a balloon and advanced to the area to be treated. The guidewire provides the
24 necessary steerability for lesion passage. The guidewire is advanced across the
25 lesion, or "wires" the lesion, in preparation for the advancement of a polyethylene,
26 polyvinyl chloride, polyolefin, or other suitable substance balloon catheter across the
27 guide wire. The balloon, or dilatation, catheter is placed into position by sliding it
28 along the guide wire. The use of the relatively rigid guide wire is necessary to
29 advance the catheter through the narrowed lumen of the artery and to direct the
30 balloon, which is typically quite flexible, across the lesion. Radiopaque markers in
31 the balloon segment of the catheter facilitate positioning across the lesion. The
32 balloon catheter is then inflated with contrast material to permit fluoroscopic viewing

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1 during treatment. The balloon is alternately inflated and deflated until the lumen of
2 the artery is satisfactorily enlarged.

3 Unfortunately, while the affected artery can be enlarged, in some instances the
4 vessel restenoses chronically, or closes down acutely, negating the positive effect of
5 the angioplasty procedure. In the past, such restenosis has frequently necessitated
6 repeat PTCA or open heart surgery. While such restenosis does not occur in the
7 majority of cases, it occurs frequently enough that such complications comprise a
8 significant percentage of the overall failures of the PTCA procedure, for example,
9 twenty-five to thirty-five percent of such failures.

10 To lessen the risk of restenosis, various devices have been proposed for
11 mechanically keeping the affected vessel open after completion of the angioplasty
12 procedure. Such mechanical endoprosthetic devices, which are generally referred
13 to as stents, are typically inserted into the vessel, positioned across the lesion, and
14 then expanded to keep the passageway clear. Effectively, the stent overcomes the
15 natural tendency of the vessel walls of some patients to close back down, thereby
16 maintaining a more normal flow of blood through that vessel than would be possible
17 if the stent were not in place.

18 Various types of stents have been proposed, although to date none has
19 proven satisfactory. One proposed stent involves a tube of stainless wire braid.
20 During insertion, the tube is positioned along a delivery device, such as a catheter,
21 in extended form, making the tube diameter as small as possible. When the stent
22 is positioned across the lesion, it is expanded, causing the length of the tube to
23 contract and the diameter to expand. Depending on the materials used in
24 construction of the stent, the tube maintains the new shape either through
25 mechanical force or otherwise. For example, one such stent is a self-expanding
26 stainless steel wire braid. Other forms of stents include various types tubular metallic
27 cylinders expanded by balloon dilatation. One such device is referred to as the
28 Palmaz stent, discussed further below.

29 Another form of stent is a heat expandable device. This device, originally
30 designed using NITINOL by Dotter has recently been modified to a new tin-coated,
31 heat expandable coil by Regan. The stent is delivered to the affected area on a
32 catheter capable of receiving heated fluids. Once properly positioned, heated saline

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1 is passed through the portion of the catheter on which the stent is located, causing
2 the stent to expand. Numerous difficulties have been encountered with this device,
3 including difficulty in obtaining reliable expansion, and difficulties in maintaining the
4 stent in its expanded state.

5 Perhaps the most popular stent presently under investigation in the United
6 States is referred to as the Palmaz stent. The Palmaz stent involves what may be
7 thought of as a stainless steel cylinder having a number of slits in its circumference,
8 resulting in a mesh when expanded. The stainless steel cylinder is delivered to the
9 affected area by means of a balloon catheter, and is then expanded to the proper
10 size by inflating the balloon.

11 Significant difficulties have been encountered with all prior art stents. Each
12 has its percentage of thrombosis, restenosis and tissue in-growth, as well as varying
13 degrees of difficulty in deployment. Another difficulty with at least some of prior art
14 stents is that they do not readily conform to the vessel shape. In addition, the
15 relatively long length of such prior art stents has made it difficult to treat curved
16 vessels, and has also effectively prevented successful implantation of multiple such
17 stents. Anticoagulants have historically been required at least for the first three
18 months after placement. These and other complications have resulted in a low level
19 of acceptance for such stents within the medical community, and to date stents have
20 not been accepted as a practical method for treating chronic restenosis.

21 Thus there has been a long felt need for a stent which is effective to maintain
22 a vessel open, without resulting in significant thrombosis, which may be easily
23 delivered to the affected area, easily expanded to the desired size, easily conformed
24 to the affected vessel, and easily used in multiples to treat curved vessels and
25 varying lengths of lesions.

26 Summary of the Invention

27 The present invention substantially reduces the complications and overcomes
28 the limitations of the prior art devices. The endovascular support device of the
29 present invention comprises a device having very low mass which is capable of
30 being delivered to the affected area by means of a slightly modified conventional
31 balloon catheter similar to that used in a standard balloon angioplasty procedure
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1 The support device of the present invention may then be expanded by normal
2 expansion of the balloon catheter used to deliver the stent to the affected area, and
3 its size can be adjusted within a relatively broad range in accordance with the
4 diagnosis of the treating physician.

5 Because of the range of diameters through which the support device of the
6 present invention may be expanded, it may be custom expanded to the specific
7 lesion diameter, and is readily conformable to the vessel shape. In addition, a
8 plurality of support devices of the present invention may be readily implanted in a
9 number commensurate with the length of the lesion under treatment. As a result,
10 curved or "S" shaped vessels may be treated.

11 The stent, or endovascular support device, of the present invention may
12 preferably be comprised of implantable quality high grade stainless steel, machined
13 specially for intravascular applications. The support device may comprise, in effect,
14 a metal circle or ellipsoid formed to create a plurality of axial bends, thereby
15 permitting compression of the stent onto a delivery catheter, and subsequent
16 expansion once in place at the affected area.

17 It is one object of the present invention to provide a stent which substantially
18 overcomes the limitations of the prior art.

19 It is a further object of the present invention to provide a stent capable of
20 being implanted simply and reliably.

21 Another object of the present invention is to provide a stent which does not
22 result in significant thrombosis at the point of implant.

23 Yet another object of the present invention is to provide a stent which can be
24 selectively sized in accordance with the anatomic configuration dictated by the lesion
25 itself.

26 A still further object of the present invention is to provide a method for
27 supplying an endovascular support device which permits a plurality of such devices
28 to be implanted commensurate with the length of the lesion under treatment.

29 These and other objects of the present invention can be better appreciated
30 from the following detailed description of the invention, taken in conjunction with the
31 attached drawings.

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Figures

Figure 1 shows a perspective view of an endovascular support device constructed according to the present invention, in its expanded form.

Figure 2 shows a support device constructed according to the present invention and compressed onto a balloon catheter.

Figure 3 shows a support device compressed onto a balloon catheter as shown in Figure 2, and positioned within a sectioned portion of an affected area of a artery or other vessel.

Figure 4 shows a support device according to the present invention in its expanded form within a sectioned portion of a vessel including a lesion.

Figure 5 shows a support device of the present invention in its expanded form within a sectioned portion of a lesion after removal of the balloon catheter.

Figures 6a-b show alternative configurations of a support device according to the present invention.

Detailed Description of the Invention

Referring first to Figure 1, an endovascular support device 10, referred to hereinafter more conveniently as a stent, constructed in accordance with the present invention can be seen in perspective view. The stent 10 of Figure 1 is shown in its expanded form, prior to compression over a suitable delivery system as discussed in detail hereinafter.

In a preferred embodiment, the stent 10 comprises a single piece of material, bent to form a plurality of upper axial turns 12 and lower axial turns 14. In the embodiment shown in Figure 1, four upper turns 12 are connected to the four lower turns 14 by substantially straight segments 16. The axial turns 12 and 14 can be seen to permit the stent 10 to be compressed or expanded over a wide range while still maintaining significant mechanical force, such as required to prevent a vessel from restenosing. While a preferred embodiment comprises a single piece of material, in some instances a suitably welded wire may be acceptable.

It will be appreciated that the number of turns 12 and 14 can vary over a reasonably wide range, and may in fact vary between two and ten such turns or peaks. However, it is currently believed that the optimum number of turns or peaks will range between three and five for most applications, and particularly for

1 cardiovascular applications.

2 The stent 10 is preferably constructed of implantable materials having good
3 mechanical strength. An embodiment which has proven successful in preliminary
4 testing is machined from 316LSS implantable quality stainless steel bar stock. The
5 bar stock is machined to form substantially a toroid, which is then acid etched in
6 phosphoric and sulfuric acid at approximately 180. to 185. to break the edges. The
7 etched toroid is then plated with copper to avoid galling and to provide lubricity.

8 The copper plated toroid is then bent to the shape of the stent 10 shown in
9 Figure 1, after which the copper plating is stripped from the stent. The stent is then
10 returned to the acid bath to reduce the wire size to the desired diameter, which is
11 in the range of 0.002" to 0.025". It is presently believed that the optimum wire size
12 for the final product is in the range of 0.008" to 0.009". It will be appreciated that the
13 strength of the stent -- that is, its ability to prevent restenosis -- is inversely
14 proportional to the number of peaks or turns in the stent, so that stents having a
15 greater number of turns will typically be formed of larger wire diameters. Finally,
16 although not required in all cases, the outside of the stent may be selectively plated
17 with platinum to provide improved visibility during fluoroscopy. The cross-sectional
18 shape of the finished stent may be circular, ellipsoidal, rectangular, hexagonal,
19 square, or other polygon, although at present it is believed that circular or ellipsoidal
20 may be preferable.

21 The minimum length of the stent, or the distance between the upper turns 12
22 and lower turns 14, is determined in large measure by the size of the vessel into
23 which the stent will be implanted. The stent 10 will preferably be of sufficient length
24 as to maintain its axial orientation within the vessel without shifting under the
25 hydraulics of blood flow (or other fluid flow in different types of vessels), while also
26 being long enough to extend across at least a significant portion of the affected
27 area. At the same time, the stent should be short enough as to not introduce
28 unnecessarily large amounts of material as might cause undue thrombosis. Typical
29 cardiovascular vessels into which the stent 10 might be implanted range from 1.5
30 millimeters to five millimeters in diameter, and corresponding stents may range from
31 one millimeter to two centimeters in length. However, in most instances the stent will
32 range in length between 3.5 millimeters and 6 millimeters. Preliminary testing of

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1 stents having a length between 3.5 millimeters and 4.5 millimeters has been
2 performed with good success outside the United States, and testing on animals is
3 also ongoing.

4 Once the wire size of the stent 10 has been reduced to the desired size, the
5 stent 10 may be crimped onto a balloon 100, as shown in Figure 2, for delivery to
6 the affected region 102 of a vessel 104 such as a coronary artery. For the sake of
7 simplicity, the multiple layers of the vessel wall 104 are shown as a single layer,
8 although it will be understood by those skilled in the art that the lesion typically is
9 a plaque deposit within the intima of the vessel 104.

10 One suitable balloon for delivery of the stent 10 is manufactured by Advanced
11 Cardiovascular Systems, Inc., of Santa Clara, California ("ACS"), and is eight
12 millimeters in length with Microglide® on the shaft only. The stent-carrying balloon
13 100 is then advanced to the affected area and across the lesion 102 in a
14 conventional manner, such as by use of a guide wire and a guide catheter (not
15 shown). A suitable guide wire is the .014" Hi Torque Floppy manufactured by ACS,
16 and a suitable guiding catheter is the ET.076 lumen guide catheter, also
17 manufactured by ACS.

18 Once the balloon 100 is in place across the lesion 102, as shown in Figure
19 3, the balloon 100 may be inflated, again substantially in a conventional manner. In
20 selecting a balloon, it is helpful to ensure that the balloon will provide radially uniform
21 inflation so that the stent 10 will expand equally along each of the peaks. The
22 inflation of the balloon 100, shown in Figure 4, causes the expansion of the stent 10
23 from its crimped configuration back to a shape substantially like that shown in Figure
24 1. The amount of inflation, and commensurate amount of expansion of the stent 10,
25 may be varied as dictated by the lesion itself, making the stent of the present
26 invention particularly flexible in the treatment of chronic restenosis.

27 Because of the inflation of the balloon, the lesion 102 in the vessel 104 is
28 expanded, and causes the arterial wall of the vessel 104 to bulge radially, as
29 simplistically depicted in Figure 4. At the same time, the plaque deposited within the
30 intima of the vessel is displaced and thinned, and the stent 10 is embedded in the
31 plaque or other fibrotic material adhering to the intima of the vessel 104.
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1 Following inflation of the balloon 100 and expansion of the stent 10 within the
2 vessel 104, the balloon is deflated and removed. The exterior wall of the vessel 104
3 returns to its original shape through elastic recoil. The stent 10, however, remains
4 in its expanded form within the vessel, and prevents further restenosis of the vessel.
5 The stent maintains an open passageway through the vessel, as shown in Figure 4,
6 so long as the tendency toward restenosis is not greater than the mechanical
7 strength of the stent 10. Because of the low mass of the support device 10 of the
8 present invention, thrombosis is less likely to occur. Ideally, the displacement of the
9 plaque deposits and the implantation of the stent 10 will result in a smooth inside
10 diameter of the vessel 104, although this ideal cannot be achieved in all cases.

11 One of the advantages of the stent 10 is that multiple stents may be used in
12 the treatment of a single lesion. Thus, for example, in the event the affected area
13 shown in Figures 3 and 4 was longer than the stent 10, additional stents 10 could
14 be positioned elsewhere along the lesion to prevent restenosis. In preliminary
15 testing, up to four stents have been used successfully along a single lesion. Due
16 to the conformability of the stent 10, not only can varying lesion lengths be
17 treated, but curved vessels and "S" shaped vessels may also be treated by the
18 present invention. In instances where it is known in advance that multiple stents will
19 be the preferred method of treatment, a plurality of such stents may be positioned
20 along a single balloon catheter for simultaneous delivery to the affected area. *as shown in Figure 7*

21 As discussed above, the number of peaks or turns 12 and 14 in the stent 10
22 may vary between two and ten. To this end, shown in Figures 6a and 6b are two
23 alternative configurations of the stent 10. The alternative embodiment shown in 6a
24 can be seen to have three upper and three lower peaks or turns, while the
25 embodiment shown in Figure 6b can be seen to have ten upper and ten lower
26 peaks.

27 While the primary application for the stent 10 is presently believed to be
28 treatment of cardiovascular disease such as atherosclerosis or other forms of
29 coronary narrowing, the stent 10 of the present invention may also be used for
30 treatment of narrowed vessels in the kidney, leg, carotid, or elsewhere in the body
31 In such other vessels, the size of the stent may need to be adjusted to compensate
32 for the differing sizes of the vessel to be treated, bearing in mind the sizing

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1 guidelines provided above.

2 Having fully described a preferred embodiment of the invention, those skilled
3 in the art will immediately appreciate, given the teachings herein, that numerous
4 alternatives and equivalents exist which do not depart from the present invention.
5 It is therefore to be understood that the present invention is not to be limited by the
6 foregoing description, but only by the appended claims.
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